

**REMARKS**

Favorable reconsideration of this application in the light of the amendments and the following discussion is respectfully requested. Applicant appreciates the cooperation of Examiner Thahn in discussing this application during the telephone interview with applicant's undersigned counsel on June 15, 2004. Although agreement was not reached during the telephone interview as to the patentability of the claims, there was an advance in the mutual understanding of the invention and the Kravitz reference. In particular, there was a discussion of the possibility of adding structural limitations to the claims as to the device employed in the method to distinguish over Kravitz.

Claims 1 and 28 have been amended to more particularly define the invention. Support for the amendments to claims 1 and 28 can be found, for example, in the specification at page 6 lines 3-5, page 7 lines 26-27, page 8 lines 5-7 and lines 15-18, page 9 lines 13-14, and the drawings. No new matter has been added. Claims 1-12 and 28-30 remain in the application for consideration.

**Claim Rejections - 35 USC § 102**

Claims 1-2, 7-10, 12 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kravitz (U.S. Patent No. 3,620,209).

The Office Action indicates that Kravitz teaches a method of reducing pain associated with skin penetration at a site with a needle comprising urging a skin-engaging surface (formed by 32 on the casing) of a pressure member (10) against the skin (12). The Examiner has taken the position that it is inherent that stimulation of the large diameter afferent sensory fibers and blocking of pain signal from the small diameter afferent pain nerve fibers in the skin proximate the site occurs since the device of Kravitz is similar in structure with the claimed device of

applicant. The aperture is considered to be 14 where the needle / hypodermic syringe (16) is to be inserted. Further, Kravitz discloses that the pain normally associated with the injection at the area is reduced or minimal. (See abstract). Further, at col. 2, lines 43-49, Kravitz discloses that the stimulation of the pain center of the skin can be enhanced with the studs or projections (32), which extend outwardly from the casing (10). Kravitz further discloses that his device is for reducing pain of injection and to lessen the pain associated with such injections by pressing the device (case 10) against the skin. With respect to the language “to thereby depress the skin with sufficient force” (deemed “functional language” in the Office Action), the prior art was considered to be capable of performing the intended use lacking any further structural distinguishing features. Although it was acknowledged that applicant has a method claim, it was considered inherently encompassed by the use of Kravitz’s device. It was suggested to claim a distinguishing structural feature or a distinguishing method step that is not inherently performed by the device of Kravitz.

#### **Response to Claim Rejections - 35 USC § 102**

Applicants respectfully traverse the rejection of claims 1-2, 7-10, 12 and 28-30 as being unpatentable over Kravitz. The method of Kravitz relies solely on vibrations at the surface of the skin. While applicant continues to maintain that Kravitz does not teach or suggest urging a skin engaging surface of a pressure member against the skin of a patient proximate the site, to thereby depress the skin with sufficient force to stimulate the large diameter afferent sensory nerve fibers in the skin proximate the site and at least partially block pain signals from the small diameter afferent pain nerve fibers in the skin proximate the site, claims 1 and 28 have been amended to include structural features clearly lacking in Kravitz in order to advance prosecution of the application.

Thus, claim 1 has been amended to define the pressure member utilized in the method as “having a skin engaging surface that is relatively broad in relation to the thickness of the pressure member.” In contrast, the Kravitz device provides a relatively narrow, horseshoe-shaped skin engaging surface. As shown in the drawings, the thickness of the Kravitz device, from the ends of the projections 32 to the opposite surface of the casing 10, is greater than the breadth of the skin engaging surface. This is due, at least in part, to the fact that the casing 10 of Kravitz holds the vibratory motor and power source required by Kravitz and the reliance by Kravitz on vibration to block pain.

Accordingly, Kravitz fails to disclose all of the elements of the claimed invention, arranged as in the claim. The rejection of claims 1 and 28 as anticipated by Kravitz should be withdrawn. Claims 2, 7-10, 12, 29 and 30 all depend from either claim 1 or claim 28, and are patentable over Kravitz at least on that basis.

#### **Claim Rejections - 35 USC § 103**

Claims 3-6 and 11 have rejected under 35 U.S.C. 103(a) as being unpatentable over Kravitz.

It is asserted that Kravitz discloses the claimed invention except for the material of the pressure member to be flexible, polymeric rigid or metal. As conceded by the Examiner, Kravitz is silent to the materials of the pressure member. However, the Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials of the pressure member to suit the area to which it would applied to, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice.

With respect to claim 11, the Examiner acknowledges that Kravitz does not show a generally cloverleaf shape pressure member. Again, however, the Examiner takes the position that it would have been an obvious design choice to modify the horseshoe or u-shaped design of the Kravitz with a cloverleaf shape lacking any criticality of the shape. The Examiner is taking the position that matters relating to ornamentation only, which have no mechanical function, cannot be relied upon to patentably distinguish the claimed invention from the prior art. The particular shape of a product is of no patentable significance since it appears to be a matter of choice that a person of ordinary skill in the art would find obvious absent persuasive evidence that the particular configuration of the claimed container was significant.

**Response to Claim Rejections - 35 USC § 103**

Applicants respectfully traverse the rejection of claims 3-6 and 11 as unpatentable over Kravitz. These claims depend, either directly or indirectly, from claim 1 and are patentable at least on that basis. The rejections should therefore be withdrawn.

Moreover, claim 3 further requires that the pressure member be “comprised of a material that is flexible enough to substantially conform to the contours of the skin in the vicinity of the site as the pressure member is urged against the skin.” Kravitz lacks any suggestion for forming its casing of such a flexible material, and further lacks any suggestion for the desirability of using such a material. The mere allegation that the differences between the claimed subject matter and the prior art are obvious does not support a prima facie case of unpatentability. *In re Soli*, 137 USPQ 797 (CCPA 1963). There is no motivation to be found in the art for modifying Kravitz as proposed by the Examiner.

Claim 11 also further defines over Kravitz, by requiring the perimeter of the pressure member to define a generally cloverleaf shape, a shape the Examiner admits is not suggested by



Kravitz. Contrary to the Examiner's assertion, the shape defined by claim 11 is not merely ornamental. As noted in the specification, for example at page 9 lines 14-17, such a shape facilitates handling of the pressure member, an advantage with the claimed method, where the pressure member is urged against and depresses the skin of the patient. On the other hand, there would be no motivation to modify Kravitz as proposed in the Office Action, as Kravitz provides arm straps 18 and 20 to hold the device in position.

For all of these reasons, a prima facie case of obviousness of the claims 3-6 and 11 based upon Kravitz has not been established. The rejections should therefore be withdrawn.

### CONCLUSION

Favorable reconsideration of the present application and the passing of this case to issue with all claims allowed are courteously solicited. In the event the Examiner would prefer language other than that currently set forth in the claims, or should the Examiner wish to discuss any other aspect of this application, applicant's attorney suggests a telephone interview in order to expedite the prosecution of the application.

Respectfully submitted,

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